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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/805,550	03/13/2001	Pramod B. Mahajan	0964D	2785

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EXAMINER
HELMER, GEORGIA L

ART UNIT	PAPER NUMBER
1638	8

DATE MAILED: 12/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/805,550	MAHAJAN ET AL.	
	Examiner	Art Unit	
	Georgia L. Helmer	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *04 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-74* is/are pending in the application.

4a) Of the above claim(s) *8-74* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Status of the Claims and Election

1. Receipt is acknowledged of Applicant's response to the restriction requirement filed October 4, 2002. Applicant elected Group I (claims 1-7), with traverse. Claims 1-74 are pending. Claims 8-74 are nonelected. Applicant's traversal is on the ground(s) that the search of Groups I and II-III will rely primarily on the search of Group I, and therefore that doing a search for all the groups would not be a burden. This is nonpersuasive because even if a search of the prior art for one group may overlap with that of another group, they are not coextensive of each other, and thus would pose serious burden on the Examiner. Applicant traverses Groups II and III as being unrelated, saying primarily that these groups have the same starting material, have the same classification, and therefore are related. This is unpersuasive because even though the Groups have the same starting material(s), they have different steps and produce different results. And even though they have the same classification identification, this does not mean they are identical. In fact these groups have been deemed patentably distinct, as indicated by the restriction requirement.

Therefore, the restriction requirement is deemed proper and is made FINAL.

Claims 1-7 are examined in the instant Office Action.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

3. Claims 2-7 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,235,972. Although the conflicting claims are not identical, they are not patentably distinct from each other. The recombinant expression cassette of claim 2, comprising DNA encoding the polypeptide of SEQ ID NO: 2, is obvious over the claims of 6,235,972, which are drawn to the same DNA. It would have been obvious to use the DNA in an expression cassette to transform host cells and plants.

Claim Rejections - 35 USC § 101

4. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1-7 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility.

Claims 1-7 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

- Claim 1 (a), drawn to an isolated protein comprising a polypeptide having at least 20 contiguous amino acids from the polypeptide of SEQ ID Nos. 2 or 4, lacks a recitation of function. This is because 20 contiguous amino acids of SEQ ID No.2 would allow 385 amino acids of nonidentity, and the region essential for protein activity may be in the nonidentical region. This is because 20 contiguous amino acids of SEQ ID No.4 would allow 348 amino acids of nonidentity, and the region essential for protein activity may be in the nonidentical region. It is thus unclear as to how this sequence would be useful, lacking its functional activity.
- Claim 1 (b), drawn to a polypeptide having of SEQ ID No. 2 or 4, lacks a recitation of function. The specification does not provide a specific or credible utility for these proteins.
- Claim 1 (c), drawn to a polypeptide having at least 70% sequence identity over the entire length of the polynucleotide of SEQ ID No. 2 or 4, lacks a recitation of function. This is because the 70% sequence identity would allow for a 30% lack

of sequence identity in the region essential for protein activity. It is thus unclear as to how this sequence would be useful lacking its functional activity.

- Claim 1 (d) drawn to a polypeptide encoded by a polynucleotide which selectively hybridizes, under stringent hybridization conditions and a wash in 0.1XSSC at 60 C, to a polynucleotide of SEQ ID NOS: 1 and 3. Such a polynucleotide encompasses a dipeptide, which lacks a recited function.

Therefore, because of the reasons discussed above, the claimed sequences do not have a real world use and therefore lack utility.

Claim Rejections - 35 USC § 112-1st, enablement

6. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically, since the claimed invention lacks utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention, without undue experimentation.

7. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claims are drawn to an isolated protein comprising a polypeptide having at least 20 contiguous amino acids from the polypeptide of SEQ ID Nos: 2 or 4, a polypeptide of SEQ ID NO: 2 or 4, a polypeptide having at least 70% sequence identity to SEQ ID NO: 2 or 4, or to a polypeptide encoded by a polynucleotide that will hybridize under stringent conditions to SEQ ID NO: 1 or 3. The claims are also drawn to an expression vector that will express any of these polypeptides, and to host cells and plants transformed therewith. However, the specification only teaches that a RAD23 gene of yeast was known and that Applicant believes that the disclosed sequences are of a maize RAD23. Yet, the specification provides no support for this assertion. There is no evidence provided that SEQ ID NO: 2 and 4 have similar structural features to the yeast RAD23 gene, nor is there any evidence regarding the functional activity of the claimed polypeptides. In fact, the specification fails to provide guidance with regard to how one skilled in the art would evaluate SEQ ID NO: 2 or 4 for a specific activity, much less any of the other sequences that are encompassed by the claims.

Sequence homology is not sufficient to predict function of encoded sequences. See the teachings of Doerks (TIG 14, no. 6: 248-250, June 1998), where it states that computer analysis of genome sequences is flawed, and "overpredictions are common because the highest scoring database protein does not necessarily share the same or even similar functions" (the last sentence of the first paragraph of page 248). Doerks also teaches homologs that did not have the same catalytic activity because active site residues were not conserved (page 248, the first sentence of the last paragraph). In addition, Smith et al (Nature Biotechnology 15:1222-1223, November 1997) teach that "there are numerous cases in which proteins of very different functions are homologous" (page 1222, the first sentence of the last paragraph). Also, Brenner (TIG 15, 4:132-133,

April 1999) discusses the problem of inferring function from homology, stating that "most homologs must have different molecular and cellular functions" (see the second full paragraph of the second column of page 132, for example). Furthermore, Borks (TIG 12, 10:425-427, October 1996) teaches numerous problems with the sequence databases that can result in the misinterpretation of sequence data.

For example and more specifically, identification of related sequences that will encode enzymes having a specific activity is particularly problematic, and cannot be determined merely by similarity of DNA or amino acid sequences. Van de Loo et al (An oleate 12-hydroxylase from Ricinus communis L. is a fatty acyl desaturase homolog. Proc, Natl. Acad. Sci. USA 92, 6743-6747, July 1995) teach that sequences encoding fatty acid hydroxylase activity are highly similar to other sequences that do not encode a hydroxylase, but instead encode a fatty acyl desaturase (see the abstract, at least). In fact, Van de Loo et al (An oleate 12-hydroxylase from Ricinus communis L. is a fatty acyl desaturase homolog, Proc, Natl. Acad. Sci. USA 92, 6743-6747, July 1995) teach that a change in only four amino acids will convert a desaturase gene to a hydroxylase gene (see the abstract, at least). Thus, if sequences are identified only by similarity to other sequences that are known, one cannot conclude on this basis alone that these sequences also will encode a protein having said activity without additional evidence of the functionality or more knowledge of the particular structural features that are required for conferring this function.

Given the recognition of those skilled in the art of the unpredictability of using the sequences of SEQ ID NO: 2 or 4, or to identify other polypeptides having the

characteristics of SEQ ID NO: 2 or 4 since specific motifs and structural features are not described and since no function of the polypeptide is described, as stated above; the lack of working examples of any sequences, including those of SEQ ID NO: 2 or 4; and given the absence of guidance for how to identify and evaluate any sequences encompassed by the claims and how to use them; and given the breadth of the claims, which encompass any plant, any polypeptide having 70% identity, any polypeptide having 20 contiguous amino acids identical to SEQ ID NO: 2 or 4; it would require undue experimentation to make and/or use the claimed invention.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Claim Rejections - 35 USC § 112-first,

Written Description

8. The following is a quotation of the first paragraph of 35 U.S.C. 112-first,

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to

reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 1 (c), is drawn to a polypeptide having at least 70% sequence identity over the entire length of the polynucleotide of SEQ ID No. 2 or 4. However, Applicant does not identify structural features necessary to describe features of SEQ ID NO: 2 or 4, which distinguish from any polypeptide. This is because the 70% sequence identity would allow for a 30% lack of sequence identity in the region essential for protein activity. In addition, in claim 1 (d), it is drawn to a polypeptide encoded by a polynucleotide which hybridizes to SEQ ID Nos: 1 or 3. However, the claims do not specify either a particular structure or a particular function for the claimed polypeptide. Applicant is claiming a genus of sequences, yet there is no description of the structural feature that defines the genus. In addition, there is no indication of what functional activity common to the genus is conferred by said structural features.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed, Cir. 1997), where it states: "The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . ."

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application

was filed. (See, Written Description Examination Guidelines (published in Federal Registry/Vol. 66, No.4/Friday, January 5, 2001/Notices).

Claim Rejections - 35 USC § 112-second

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, a "member" implies a part of a group; substituting "polypeptide" is suggested.

In claim 1 (d), drawn to a polypeptide encoded by a polynucleotide which selectively hybridizes, under "stringent hybridization conditions" to a polynucleotide of SEQ ID NOS: 1 and 3.

- "selectively hybridize" is unclear because the parameters for the hybridization, such as temperature, salts, concentration, and time, are not disclosed.
- "stringent hybridization conditions" is unclear because specific conditions, as discussed above for "selectively hybridize", need to be defined.

Clarification and/ or correction is required.

REMARKS

12. No claims are allowed.

13. SEQ ID NO: 2 and 4 are free of the prior art of record. Claims 1-7 are free of the prior art.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer
Patent Examiner
Art Unit 1638
November 22, 2002

ELIZABETH F. McELWAIN
PRIMARY EXAMINER
GROUP 1600